



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy/Wholesaler Level

Date: 06 July 2021

EL (21)A/16

Our Ref: MDR 387-06/21

Dear Healthcare Professional,

Galderma UK

Tetralysal 300mg Hard Capsules

PL 10590/0019

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| 853 | 07-2023 | 56 | 17 Feb 2021 |
| 869 | 12-2023 | 56 | 21 May 2021 |
| 881 | 03-2024 | 28 | 26 May 2021 |

Active Pharmaceutical Ingredient: Lymecycline

Brief description of the problem

Galderma UK would like to notify you of an error identified by Galderma regarding specific batches of Tetralysal 300mg Hard Capsules, sold and distributed in the UK. The error identified relates to approved safety-related variations to the PIL that were not implemented, resulting in an older version of artwork being used and packed within finished batches. Additional warnings, precautions and side effects have been updated in the latest version of the PIL.

| Information on current PIL | Corrected information missing within the PIL |
|--|---|
| <i>Other medicines and Tetralysal Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.</i> | <i>You should tell your doctor if you are taking any treatment with lithium, this medicine may increase the lithium levels.</i> |
| <i>Other medicines and Tetralysal Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.</i> | <i>Avoid use with penicillins (and other types of antibiotics),</i> |



| Information on current PIL | Corrected information missing within the PIL |
|---|--|
| <p><i>Possible side effects;</i> <i>Not known: frequency cannot be estimated from the available data</i></p> <ul style="list-style-type: none">- <i>disturbances of eyesight</i>- <i>severe or persistent headaches or visual disturbances.</i>- <i>vomiting (being sick)</i> | <p>- <i>disturbances of eyesight*</i></p> <p><i>*the presence of symptoms, such as visual disturbances, or headaches, could be attributed to increased pressure in the brain (intracranial hypertension). You should stop taking Tetralysal if there is any evidence of pressure increase in the brain. Benign intracranial hypertension, symptoms of which may include headache, vomiting, visual disturbances (blurred vision, blind spots or double vision), or permanent visual loss have been reported with tetracycline therapy.</i></p> |
| <p><i>Possible side effects:</i> <i>(No details re: <u>depression, nightmare and systemic lupus erythematosus</u>)</i></p> | <p>- <i>depression</i> - <i>nightmare</i></p> <p><i>The following side effects may occur during treatment with the class of medicines to which Tetralysal belongs (the tetracyclines): - systemic lupus erythematosus (an allergic condition that causes joint pain, skin rashes or fever)</i></p> |

Advice for healthcare professionals

Healthcare professionals are advised to exercise caution when dispensing the product and where possible, provide an updated PIL. There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Where available, Galderma UK will be providing the updated PIL with all future deliveries for the affected batches.

The correct PIL is available from the electronic medicines compendium (EMC) website by clicking on the link below:

- [PIL for Tetralysal 300mg Hard Capsules](#)

Further Information

For more information, medical information queries or replacement PIL enquiries, please contact: medinfo.uk@galderma.com

For stock control queries, please contact: sales.uk@galderma.com



Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574**